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FAX COVER SHEET

Date: **September 19, 2003**
From: **Roger H. Criss**
Client/Matter #: **0147-1**
Re: **Serial No. 09/828,330, Filed April 6, 2001**

Pages sent (including cover): 18

RECIPIENT	FIRM	CC:	FAX NUMBER
Examiner C. Nichols	**USPTO – Art Unit 1647**		**703-872-9307**

Message:

Dear Dr. Nichols:

Enclosed for your information is a copy of the Amendment after Final Rejection that has been mailed today to the USPTO. The reason that the official copy is being mailed is because a check was required for the extension of time. However, I thought that you would like a copy at this time.

Should there be any questions, please let me know.

Respectfully submitted,

Roger H. Criss
Reg. No. 25,570

Enclosure

Amendment to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claims 1-15 (canceled)

Claim 16 (currently amended): A method for the systematic, multi-tiered treatment of coronary artery disease by delivery of a formulation comprising one or more therapeutic growth factor proteins, the method comprising the steps of:

a.) selecting a patient displaying symptoms of acute coronary artery disease;

b.) administrating at least one dose of an effective amount of a first therapeutic growth factor protein formulation comprising a growth factor protein being selected from the group consisting of FGF-1, FGF-2, VEGF, and mixtures thereof, by inhalation therapy;

c.) monitoring one or more clinical indicators of acute coronary artery disease;

d.) determining, based on monitoring the one or more clinical indicators of coronary artery disease, whether an additional dose of a therapeutic growth factor protein formulation is necessary;

e.) depending on the results of the step d.), administering one or more additional doses of a second growth factor protein formulation comprising a growth factor protein being selected from the group consisting of FGF-1, FGF-2, VEGF, and mixtures thereof; and

f.) repeating steps c.) through e.) until there is a clinical indication of amelioration of the symptoms of acute coronary artery disease in the patient, or until there is a contraindication to continued treatment.

Claim 17 (currently amended): The method of claim 16[[. (New)]], wherein the second growth factor protein is administered by a method of delivery more invasive than the method of delivery utilized for administration of the first growth factor protein formulation.

Claim 18 (currently amended): The method of claim 16[[. (New)]], wherein the second growth factor protein is administered by the same method of delivery utilized for administration of the previous dose.

Claim 19 (currently amended): The method of claim 16[[. (New)]], wherein the one or more clinical indicators of acute coronary artery disease are selected from the group consisting of levels of CPK-MB, electrocardiogram tracings, and chest pain.

Claim 20 (canceled)

Claim 21 (currently amended): The method of claim 16[[. (New)]], wherein the symptoms of acute coronary artery disease are brought on by a condition selected from the group consisting of myocardial infarct, unstable angina, and acute anginal attack.

Claim 22 (currently amended): The method of claim 16[[. (New)]], wherein the method of delivery of the second growth factor protein formulation is selected from the group consisting of oral inhalation, intravenous administration, intracoronary infusion, intrapericardial injection, myocardial introduction via catheter during cardiac catherization, and direct myocardial injection.

Claim 23 (currently amended): The method of claim 16[[. (New)]], wherein the growth factor formulation administered in step e.) and subsequent steps is the same as the growth factor formulation administered initially.

Claim 24 (currently amended): The method of claim 16[[. (New)]], wherein the growth factor formulation administered in step e.) and subsequent steps is different from the growth factor formulation administered initially.

Claims 25-34 (canceled)

Claim 15 (currently amended): A method for the systematic, multi-tiered treatment of chronic coronary artery disease by delivery of a formulation comprising one or more therapeutic growth factor proteins, the method comprising the steps of:

a.) selecting a patient displaying symptoms of chronic coronary artery disease;

b.) administrating at least one dose of an effective amount of a first therapeutic growth factor protein formulation comprising a growth factor protein being selected from the group consisting of FGF-1, FGF-2, VEGF, and mixtures thereof, by inhalation therapy;

c.) monitoring one or more clinical indicators of chronic coronary artery disease;

d.) determining, based on monitoring the one or more clinical indicators of chronic coronary artery disease, whether an additional dose of a therapeutic growth factor protein formulation is necessary;

e.) depending on the results of the step d.), administering one or more additional doses of a second growth factor protein formulation comprising a growth factor protein being selected from the group consisting of FGF-1, FGF-2, VEGF, and mixtures thereof; and

f.) repeating steps c.) through e.) until there is a clinical indication of amelioration of the symptoms of chronic coronary artery disease in the patient, or until there is a contraindication to continued treatment.

Claim 16 (currently amended): The method of claim 15 [[.(New)]], wherein the amelioration of symptoms is achieved as a result of a clinically significant amount of angiogenesis.

Claim 17 (currently amended): The method of claim 15 [[.(New)]], wherein the second growth factor protein formulation is administered by the same method of delivery utilized for the administration of the previous dose.

Claim 18 (currently amended): The method of claim 15 [[.(New)]], wherein the second growth factor protein formulation is administered by a method of delivery more invasive than the method of delivery utilized for the administration of the first growth protein formulation.

Claim 19 (currently amended): The method of claim 15 [[.(New)]], wherein the one or more clinical indicators of chronic coronary artery disease are selected from the group consisting of frequency and intensity of anginal symptoms, myocardial perfusion, electrocardiogram tracings, scores on quantitative angina scales, and angiography.

Claim 40 (canceled)

Claim 20 (currently amended): The method of claim 15 [[.(New)]], wherein the method of delivery of the second growth factor protein formulation is selected from the group consisting of oral inhalation, intravenous administration, intracoronary infusion, intrapericardial injection, myocardial introduction *via* catheter during cardiac catherization, introduction during transmyocardial revascularization and direct myocardial injection.

Claim 21 (currently amended): The method of claim 15 [[.(New)]], wherein the growth factor formulation administered in step e.) and subsequent steps is the same as the growth factor formulation administered initially.

Claim 22 (currently amended): The method of claim 15 [[.(New)]], wherein the growth factor formulation administered in step e.) and subsequent steps is different from the growth factor formulation administered initially.

Claims 44-53 (canceled)

Claim 54 (new): The method of claim 16, wherein each of said first and second therapeutic growth factor protein formulations comprise FGF-1 and/or FGF-2.

Claim 55 (new): The method of claim 16, wherein each of said first and second therapeutic growth factor protein formulations comprise VEGF.

Claim 56 (new): The method of claim 25, wherein each of said first and second therapeutic growth factor protein formulations comprise FGF-1 and/or FGF-2.

Claim 57 (new): The method of claim 25, wherein each of said first and second therapeutic growth factor protein formulations comprise VEGF.

Claim 58 (new): The method of claim 16, wherein at least one of said first and second therapeutic growth factor protein formulations is a dry powder formulation.

Claim 59 (new): The method of claim 16, wherein at least one of said first and second therapeutic growth factor protein formulations is a liquid aerosol formulation.

Claim 60 (new): The method of claim 16, wherein the acute symptoms of heart disease are brought on by reperfusion injury.

Claim 61 (new): The method of claim 60, wherein the reperfusion injury is induced by a procedure selected from the group consisting of thrombolytic therapy, bypass surgery and angioplasty.